Hgb Pro

Professional Hemoglobin Testing System®

USER'S MANUAL

Read this user's manual and the Hgb Pro test strip package insert prior to use.

For *in vitro* diagnostic use

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INTENDED USE

The Hgb Pro Professional Hemoglobin Testing System® consists of a portable, battery-operated meter and single-use test strips for the quantitative measurement of total hemoglobin from capillary and venous whole blood. The System is designed for near patient testing in a professional facility, and is not intended for home use.

VALUE OF HEMOGLOBIN MEASUREMENT

Hemoglobin is the oxygen-carrying protein in red blood cells. The quantitative measurement of hemoglobin is indicated and clinically useful in acute illness as well as in general care. The normal range hemoglobin values reported in medical literature[1] are gender and age dependent:

Adult males	13.5 – 18.0 g/dL
Adult females	12.0 – 16.0 g/dL
Infants	Ranging from 14.5 – 22.5 g/dL after birth to 11.1 – 14.1 g/dL at 6 months.
Children	Gradual increase from infant to adult levels.

Low hemoglobin levels may indicate conditions such as anemia or hemorrhage. Elevated hemoglobin levels may indicate conditions such as polycythemia. A hemoglobin test may be used as part of a general screen for many types of patient populations, including the elderly, children, and women of child-bearing age, and prior to giving or receiving transfusions. Due to differences among patient populations, we recommend that each clinical site establish its own expected ranges.

Point-of-care hemoglobin test systems, using whole blood samples, are especially useful for rapid patient assessment and determination of further appropriate medical care.

CALIBRATION

The Hgb Pro meter is self-calibrating. No additional calibration is required.

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. The Hgb Pro meter is designed for use only with Hgb Pro Hemoglobin test strips.
3. Poor blood collection technique and inadequate mixing of EDTA-treated samples may affect results.
4. As with all diagnostic tests, Hgb Pro test results should be evaluated with the specific patient's condition. Any results demonstrating inconsistency with the patient's clinical status should be repeated or supplemented with additional test data.
5. Review all instructions in this User's Manual for proper technique and procedures for performing tests and using the meter.
6. While the test is in progress, do not disturb or move the meter or test strip, or press any of the meter buttons.
7. The Hgb Pro System is designed for storage and operation within a recommended temperature range of 15°C to 30°C. Do not expose the meter, test strips or patient blood sample to temperature extremes, as such exposure could affect performance.

LIMITATIONS

1. Plasma or serum cannot be used with the Hgb Pro Professional Hemoglobin Testing System. Use of arterial whole blood has not been evaluated.
2. Use of sodium citrate and dried heparin are not recommended.

INTERFERING SUBSTANCES

During clinical studies, a number of patients had identified elevated levels of bilirubin, cholesterol and triglycerides. The interferences of these substances were assessed using the interpretive guidelines of NCCLS Guidance Document EP7-A, Interference Testing in Clinical Chemistry: Approved Guideline[3]. There was no demonstrated interference of these substances on the hemoglobin determination in these analyses. No interference was observed at upper threshold concentrations of bilirubin 20 mg/dL, cholesterol 450 mg/dL and triglycerides 750 mg/dL in supportive laboratory "spiking studies."

REAGENTS

The Hgb Pro hemoglobin test strip consists of a plastic carrier and a membrane preloaded with saponin, surfactant and colorant. The test strip container is stamped with a lot-specific Lot Code and expiration date.

Note: The Lot Code for the lot number of test strips in use must be entered into the meter prior to use – see ***Lot Code Entry*** under **TEST PROCEDURE.**

DO NOT immerse the meter in liquids. DO NOT use solvents or strong caustic cleaning solutions as they may damage the outer surface of the meter. There are no other user-serviceable parts on the Hgb Pro hemoglobin meter.

Battery Indicator

low

A low battery indicator is displayed briefly during the meter self-check. It will be displayed continuously after approximately 800 tests have been performed, which indicates the battery is low and needs to be replaced. (The number of tests actually performed by the meter on the same battery will depend on individual usage patterns.) When the battery is low, the meter may shut off immediately when turned on or during a test. *A replacement battery should be installed as soon as possible after the low battery indicator is displayed.* Replacement lithium 3-volt CR2032 batteries can be obtained in most retail stores.

Battery Replacement

Step 1: Lift the test strip holder off the meter.

Step 2: Lift the battery out of the slot.

Step 3: Hold the new battery at an angle, push it into the slot and snap down. The positive (+) side of the battery should be facing up.

Note: *The new battery must be inserted within 5 minutes of removal of the old battery to avoid loss of saved settings (Lot Code, time and date.)*

Step 4: Replace the test strip holder by snapping back into place.

SPECIMEN COLLECTION

Fresh or EDTA-anticoagulated capillary or venous whole blood may be used.

If an EDTA-treated sample is refrigerated, allow it to come to room temperature prior to use. EDTA-treated blood samples should be tested within 24 hours and thoroughly mixed, using end-to-end inversion at least 8 times prior to use. Hemolyzed blood samples should not be used. Anticoagulants other than EDTA are not recommended for use.

If the Lot Code displayed on the meter does not match the Lot Code printed on the test strip container in use, change the Lot Code as follows:

Step 1: Press and hold the ▼ button until CODE flashes in the upper left-hand corner. Release the ▼ button.

Step 2: Press the ▲ or ▼ button so the displayed Lot Code **matches** the Lot Code printed on the test strip container in use. Holding down the button will enable the numbers to scroll faster. Release the button when the appropriate number is displayed.

Step 3: Accept the new Code by pressing the ⏻ button to turn the meter off.

Step 4: Turn the meter on again to perform a test.

Step 3: Prepare for a Fingerstick

Make sure the patient's hand is warm and relaxed. Use the middle or ring finger. Massage the patient's finger from the knuckle up to the tip to stimulate blood flow. Clean the sample area with alcohol and wipe dry with a sterile gauze pad.

Step 4: Prepare the Test Strip

Remove a test strip from its container. Examine the strip; Do not use if there are tears, wrinkles or debris. Do not touch the test membrane. Reseal remaining strips in the original container.

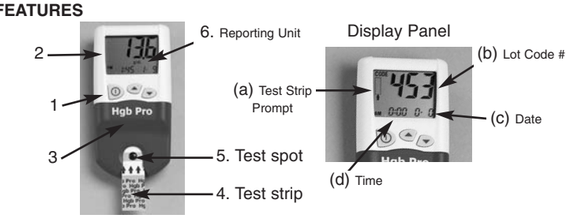
Step 5: Insert the Test Strip

Insert the test strip into the test strip holder with the notched end in first and the printing facing up. The blue stripe on the top of the strip should no longer be visible when the test strip is correctly and fully inserted.

OPERATION

The Hgb Pro meter utilizes optical reflectance at 522 nm for determination of total hemoglobin. This wavelength is within the known hemoglobin absorption spectrum (500 – 600 nm)[2]. The test strip is inserted into the meter when prompted. A background blank reading is automatically determined. A drop of whole blood is applied to the test spot on the strip. Blood immediately disperses within the membrane, contacting the reagent, lysing the red blood cells and releasing the hemoglobin. The meter's optical detectors automatically measure the change in membrane reflectance. The intensity of reflectance is inversely proportional to the hemoglobin concentration. The meter calculates and displays the total hemoglobin concentration in grams/deciliter (g/dL) or millimole/liter (mmol/L) based on a mathematical conversion. The test result will be displayed in less than 30 seconds.

FEATURES



1. Button Panel
   - **Power** ⏻ button
     Turns the meter on and off.
   - **Up** ▲ / **Down** ▼ buttons
     For use in entering Lot Code and meter settings, tagging a result and scrolling through test results in the memory.
2. Display panel
   - (a) Displays test strip prompt, (b) current Lot Code, (c) date, (d) time.
3. Test Strip Holder
   - For insertion of test strip. Can be removed for cleaning.
4. Test Strip
5. Test Spot
   - Blood sample is applied to the Test Spot membrane.
6. Reporting Unit (g/dL or mmol/L)

CAUTION: *Follow universal precautions and institutional guidelines for handling of blood samples, including the use of protective gloves. All used test strips should be considered potentially infectious, handled with care and disposed of using standard policies for disposal of medical waste.*

Reagent Preparation and Storage

1. Hgb Pro test strips are ready to use. No additional preparation is required.
2. Test strips are stable at ambient room temperature (15°C – 30°C) until the marked expiration date. Discard test strips that are past the marked expiration date.
3. Hgb Pro test strips are moisture sensitive. A dessicant is provided in the container lid. The remaining test strips should be **resealed in their original container** in order to retain the marked expiration dating. Remove only those strips needed for testing.

METER SPECIFICATIONS

Size	(L) 100 mm x (W) 55mm x (H) 17 mm
Weight	Less than 100 grams
Recommended Operating and Storage Temperature Range	15°C – 30°C
Recommended Operating Humidity Range	< 80% RH, non condensing
Battery type	Lithium 3-volt CR2032
Memory	250 test records

SERVICE AND MAINTENANCE

Routine Maintenance and Cleaning

The meter test strip holder should be cleaned after each use to remove any excess blood. The strip holder may be lifted off the meter for cleaning. Remove any residual blood or other matter on the outside of the test strip holder or the meter by using gauze dampened with an appropriate disinfectant, such as a 10% dilution of household bleach (equivalent to 0.6% hypochlorite). If excess blood is on the optical detector, it may be cleaned using a swab moistened with these cleaning solutions. Remove any residue and thoroughly dry the test strip holder and the optical detector using a lint-free tissue. Do not scratch the optical detector surface. Do not use strong, abrasive or corrosive cleaning solutions as they can damage the meter and the optical detector. After cleaning and thoroughly drying, replace the test strip holder by snapping into place. The test strip holder is a replaceable part that can be ordered through ITC customer service.

Follow the Test Procedure section in the package insert for obtaining fingerstick samples. Refer to NCCLS Documents H4-A4, Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture[4].

For fresh whole blood venous samples, collect approximately 0.1mL into an anticoagulant-free plastic syringe, and apply a blood drop to the test spot from the syringe in place of steps 7 and 8 of the test procedure. Refer to NCCLS Document H3-A5, Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture[5].

TEST PROCEDURE

The user should review all instructions in this User's Manual and the Hgb Pro Package Insert prior to using the meter. Follow the instructions in **SET-UP OPTIONS** in this manual for setting the time, date, and reporting units prior to the first use of the meter.

Materials Provided and Materials Needed But Not Provided

	Catalog No. **HGBPROKIT:**	Catalog No. **HGBMETER:**	Catalog No. **HGBTEST100:**
Materials Provided	• Hgb Pro Meter	• Hgb Pro Meter	• Hgb Pro Hemoglobin Test Strips
	• Hgb Pro User's Manual • Hgb Pro Hemoglobin Test Strips • Hgb Pro Test Strips Package Insert • Training CD ROM	• Hgb Pro User's Manual • EZ Guide	• Hgb Pro Test Strip Package Insert • EZ Guide
Materials Needed But Not Provided		• Hgb Pro Hemoglobin Test Strips • Hgb Pro Test Strip Package Insert	• Hgb Pro Meter • Hgb Pro User's Manual
	• Liquid Quality Controls (see Section **QUALITY CONTROL** in Test Strip package insert) • Incision or fingerstick device • Alcohol pad • Gauze • Bleach (for cleaning the meter)		

Step 1: Start the Meter

Press the ⏻ button to turn the meter on. The meter automatically monitors its internal circuitry and components during a brief self-check. The meter is ready when the test strip prompt, Lot Code, time and date are displayed.

Note: *To conserve the battery, the meter will automatically shut off after 2 minutes of inactivity.*

Step 2: Lot Code Entry

A specific Lot Code is assigned to each lot of Hgb Pro hemoglobin test strips to ensure optimal lot-to-lot reproducibility. **Check the Lot Code displayed on the meter to ensure it matches the Lot Code printed on the test strip container.**

Step 6: Prepare the Meter for Sample Application

The meter will automatically perform a background blank reading. It will display a flashing prompt (a blood drop next to a test strip) to indicate it is ready to receive a sample. The meter will allow 2 minutes for application of the blood sample.

Step 7: Perform a Fingerstick

Incise the underside of the fingertip (as highlighted by arrow). **Wipe away** the first drop of blood. Apply light pressure to obtain another drop of blood. Avoid "milking."

Note: *If fresh venous whole blood is to be used, perform venipuncture and collect the sample in an anticoagulant-free plastic syringe.*

Step 8: Apply Blood Sample to the Test Strip

Immediately add a drop of blood to the test strip by touching the hanging blood drop to the test spot. **(Make sure the blood drop is large enough to completely cover the test spot.)** A capillary transfer pipet may also be used to transfer the blood sample from the finger to the test strip.

Tips for applying a fingerstick blood sample to the meter:

- A single blood drop of at least 15µl of blood must be applied.
- DO NOT remove the test strip to apply the blood sample – the test strip must stay inserted in the meter. The meter may be lifted to the patient's finger for blood application.
- DO NOT touch the finger directly to the test spot membrane.
- DO NOT overfill the test spot – add enough blood to completely fill the test spot only.
- DO NOT add more blood once blood has already been applied to the test spot.

Note: *If a sample is obtained from a venipuncture, apply a blood drop (free of bubbles) to the test spot from the syringe opening or needle. Do not touch the syringe opening or needle directly onto the test spot.*

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Step 9: Read Result
The blood sample will spread and the meter will automatically begin the test. While the test is **in progress**, do not disturb or move the meter or test strip, or press any of the meter buttons.

The result will be displayed as hemoglobin units (as defined in **SET-UP OPTIONS**) in either g/dL or mmol/L in less than 30 seconds, and will remain on display for 2 minutes after test completion.

After the test is completed, remove the test strip and dispose according to standard methods for biohazard control. The meter will automatically shut off after 2 minutes of inactivity, or can be turned off by pressing the ⓘ button. The test result will be stored automatically with its date and time stamp when the meter is shut off. The meter must be reset (shut off, restart) between each test.

Test results can be tagged, viewed or erased. Follow instructions under **TAG, VIEW AND ERASE TEST RESULTS.**

REPORTABLE RANGE
The reportable range for the Hgb Pro Professional Hemoglobin Testing System is from 4.0 g/dL to 24.0 g/dL. Results under 4.0 g/dL and over 24.0 g/dL will be displayed as "Lo" and "Hi" respectively to indicate out of range results.

QUALITY CONTROL
A quality assurance program is recommended to assure the user of reliable performance of the Hgb Pro Professional Hemoglobin Testing System. Liquid quality control testing should be performed upon receipt of a new lot of test strips and once per every three months of usage.

Commercially available control material can be used for this purpose. Instructions for use of the commercial controls can be found in the Hgb Pro package insert.

SET-UP OPTIONS
Prior to the **first use** of the Hgb Pro meter, the user must enter the following settings:
- Time and date format. (12 hour or 24 hour)
- Current time and date.
- Hemoglobin reporting unit. (g/dL or mmol/L)

Entering Settings
Step 1: Lift the test strip holder off the meter.

Step 2: Turn the meter on by pressing the ⓘ button. Wait until the meter displays the Lot Code, time and date.

The meter can now be customized for time and date format, current time and date, and hemoglobin reporting units.

Select Time and Date Format:
The user can select whether to display time and date in a 12-hour AM/PM time clock with mm/dd date format (United States) or in a 24-hour time clock with dd/mm date format (Europe). (Note: the date format only contains day and month, not year. *In a leap year, the user must enter the February 29 date to ensure correct stamping of test results.*)

Step 1: Press the **SET** button once – the date and time will be displayed. Press and hold the **SET** button again until the time and date flash.
Step 2: Press the ▲ or ▼ button to select either the 12-hour time with mm/dd date format or the 24-hour time with dd/mm date format. (Note: Only these settings are available – the date and time formats cannot be individually changed.)
Step 3: To enter the current time and date, proceed to ***Enter Time and Date*** Step 2 below. If entering the current time and date is not required, then turn the meter off to accept the selected time and date format. Once accepted, the time and date format will be changed for all stored test results.

Enter Time and Date:
The user must enter the current time and date for correct stamping of test results. If proceeding from ***Select Time and Date Format*** instructions above, go directly to Step 2. Otherwise, start from Step 1.

Step 1: Press and hold the **SET** button until the time and date flash. Press the **SET** button again.
Step 2: The hour (with AM/PM if 12-hour format was selected) will flash. Press the ▲ or ▼ button to enter the hour. Press the **SET** button to accept.
Step 3: The minutes will now flash. Press the ▲ or ▼ button to enter the minutes. Press the **SET** button to accept.
Step 4: The first date selection will now flash (**mm** or **dd**). Press the ▲ or ▼ button to enter the first date selection. Press the **SET** button to accept.
Step 5: The second date selection will now flash (**dd** or **mm**). Press the ▲ or ▼ button to enter the second date selection. Press the **SET** button to accept.
Step 6: Turn the meter off to accept the entered time and date.

Select Hemoglobin Reporting Unit:
The reporting unit for hemoglobin results may be selected as either grams/deciliter (g/dL) or millimole/liter (mmol/L).

Step 1: Press the **SET** button 4 times to display the reporting unit (either **g/dL** or **mmol/L**). Press and hold the **SET** button until the unit flashes.Release the set button. Press the ▲ or ▼ button to select the appropriate reporting unit.
Step 2: Turn the meter off to accept the selected reporting unit.
Note: Once accepted, the reporting unit will be changed for all stored test results.

When selection of meter settings has been completed, replace the test strip holder onto the meter.

TAG, VIEW AND ERASE TEST RESULTS

Tag a Test Result:
A specific test result can be tagged prior to storage. Once stored, the result will flash when the user scrolls through the meter's memory. Tagging is useful for identification of QC test results.

Step 1: Perform a test, following instructions under **TEST PROCEDURE.**
Step 2: Before meter shutoff, press and hold the ▼ button. The test result will flash when the user scrolls through the memory.
Note: *The tag can be removed prior to storage only by pressing and holding the ▼ button again.*
Step 3: Turn meter off to store the test results.

Store Test Results:
The meter automatically stores up to 250 test results with a date and time stamp. When more than 250 test results are stored, the oldest test result is automatically erased. Test results are stored in ascending chronological order: the first test result displayed (sequence # 001) is the most recent one, and the last test result displayed (up to sequence # 250) is the oldest. A test result is stored when the meter shuts off (either by pressing the ⓘ button or automatic shut off after two minutes).

View Saved Test Results:
Step 1: Turn the meter on by pressing the ⓘ button. Wait until the meter displays the Lot Code, time and date. Press the ▲ button to display the test result and its sequence number (a flashing **MEM** will be displayed to the lower left of the test result). Release of the button displays the test result with its time and date stamp.
Step 2: Continue pressing the ▲ or ▼ button to scroll through test results. Holding the button will scroll more quickly.
Step 3: Turn meter off to exit the memory.

Erase Test Results:
Test results can be erased in two ways: Using the CLA function, erase either the most recent test result performed or the entire memory. The user can cancel out of erasing test results by turning off the meter (by pressing the ⓘ button) prior to display of **MEM**.

Step 1: Remove the test strip holder. Turn the meter on by pressing the ⓘ button. Wait until the meter displays the Lot Code, time and date.

Erase the Last Test Result:

Step 2: Press the **SET** button twice. **CLE** will be displayed.
Step 3: Press and hold the **SET** button until **CLE** flashes. After releasing the **SET** button, the most recent test result will be displayed.
Note: *To cancel out of the* **CLE** *function without erasing the result, turn off the meter.*
Step 4: To erase the result, press and hold the **SET** button. The test result will flash and when erased, will be replaced by **MEM###--- (### represents the test result sequence number)**. The --- symbol will replace that test result in the memory, until replaced by a new test result.

Erase the Entire Memory:
Step 2: Press the **SET** button three times. **CLA** will be displayed.
Step 3: Press and hold the **SET** button until **CLA** flashes. After releasing the **SET** button, **ALL** will appear.
Note: *To cancel out of the* **CLA** *function without erasing the entire memory, turn off the meter.*
Step 4: To erase the entire memory, press and hold the **SET** button. When the entire memory is erased, **ALL** will be replaced by **MEM---**.

Upon completion of the memory functions, turn off the meter and place the test strip holder on the meter.

TROUBLESHOOTING
An error code may be displayed when turning the meter on or performing a test. An error code may indicate a problem with blood sample application or test strip, or in the test procedure or the meter. If an error code appears, review the instructions for use and repeat the test with a new test strip. The ***Troubleshooting Guide*** gives the codes for the most common errors and the appropriate follow-up action.

If an error code persists, write down the entire error code and call ITC Technical Service at 1-800-631-5945 (1-732-548-5700). Please have the meter serial number, test strip lot number and Lot Code ready when you contact Technical Service.

Troubleshooting Guide

Error Code Displayed	Source of Error	Follow-up action
E0,E1	Meter hardware or software error.	Turn the meter off and turn on again. If the code persists, contact ITC Technical Service.
	Meter is used in direct bright sunlight.	Direct bright sunlight may interfere with the meter's optics. Move the meter out of direct bright sunlight to a location with regular room lighting or shade. Turn the meter off and turn on again. Repeat test with a new test strip.
E2	Temperature is out of range.	Move the meter to a location where ambient room temperature is within specification and allow the meter to acclimate. Turn the meter off and turn on again. Repeat test with a new test strip.
	After the blood sample is applied, the test strip was removed before the test was completed.	Once the blood sample is applied to the test strip, the strip should be left in the meter to complete the test reading. Turn the meter off and turn on again. Repeat test with a new test strip.
	Insufficient blood sample was applied.	Remove used strip and turn the meter off. Turn the meter on again and repeat test with a new test strip, ensuring the test spot is completely filled with blood.
	Test strip is damaged.	Remove test strip and turn meter off. Turn the meter on again and repeat test with a new test strip. Examine the strip before use and do not use if there are tears, wrinkles or debris.
	Incorrect sample type was used.	Fresh or EDTA-anticoagulated blood can be used. Other sample types, such as plasma, cannot be used. Repeat the test, using the correct sample type.
E4	Test strip is damaged.	Remove test strip and turn meter off. Turn the meter on again and repeat test with a new test strip. Examine the strip before use and do not use if there are tears, wrinkles or debris.
	Meter optical detector requires cleaning.	Remove test strip holder and clean the optical detector according to instructions in ***Routine Maintenance and Cleaning*** under **SERVICE AND MAINTENANCE.**
	Meter optical detector is blocked.	Do not add the blood sample prior to completion of background reading by the meter. The meter is ready for sample application when it displays a flashing test strip and blood drop prompt.

Error Code Displayed	Source of Error	Follow-up action
E4 (cont.)	Meter optical detector is blocked.	Check the optical detector to ensure blood or other matter is not present – remove the strip holder to view and clean the optical detector as needed. See ***Routine Maintenance and Cleaning*** under **SERVICE AND MAINTENANCE.**
	A used test strip was inserted into the meter.	Remove used test strip and turn the meter off. Turn the meter on again and repeat the test with a new test strip.
	The test strip was inserted incorrectly.	Review instructions under **TEST PROCEDURE** for proper insertion of test strip. Remove test strip and turn the meter off. Turn the meter on again and perform the test with a new test strip.
	Test strip holder is not installed correctly.	Remove test strip holder and install again, snapping back into place. The test strip holder should not be loose or skewed.
Meter shuts off immediately when turned on, or during a test.	Battery needs to be replaced.	Obtain and insert replacement battery according to instructions in ***Battery Replacement*** under **SERVICE AND MAINTENANCE.**
	Test Strip is removed during a test.	The meter will shut off automatically after 4 seconds if a test strip is removed during the performance of a test. Perform a new test using a new test strip.

Product Use Tips
- Review all instructions under **TEST PROCEDURE** to become proficient at using the meter and applying a blood sample to the test strip.
- Confirm that the Lot Code displayed on the meter **matches** the Lot Code printed on the test strip container. See **TEST PROCEDURE** for changing the Lot Code.

Test Strip Handling: When handling the Hgb Pro test strip, do not touch the test spot membrane.

INCORRECT

Test Strip Insertion Into Meter: Ensure the test strip is inserted into the meter with the notched end in first and the printing facing up. Do not insert the test strip with the printing facing down or the notched end toward the back, as the meter will be unable to properly read the test. Do not insert the test strip so that it is skewed.

CORRECT **INCORRECT** **INCORRECT**

Test strip is upside down. **Test Strip is skewed.**

Blood Sample Application: To help avoid sample errors, become skilled at obtaining blood with the fingerstick technique. Do not obtain a fresh whole blood sample prior to preparing the meter and test strip as described in **TEST PROCEDURE**. Do not touch the test spot membrane directly with the finger – apply only a hanging drop of blood to the test spot.

CORRECT **INCORRECT**

SAFETY STANDARDS
The Hgb Pro Professional Hemoglobin Testing System complies with the following safety standards and directives:

International Standard	Title	European Standard
UL 61010-A1	Electrical Equipment for Laboratory Use; Part 1: General requirements.	N/A
CAN/CSA-C22.2 No.1010.1	Safety requirements for electrical equipment for measurement, control and laboratory use; General requirements.	N/A
-	Council Directive 1989/336/EEC of May 1989 on the approximation of the laws of the member states relating to electromagnetic compatibility.	Directive 89/336/EEC
-	Council Directive 1992/31/EEC of 28 April 1992 amending the approximation of the laws of the member states relating to electromagnetic compatibility.	Directive 92/31/EEC
IEC 61326-1:2000-11	Safety requirements for electrical equipment for measurement, control and laboratory use – EMC requirements.	EN61326-1
IEC 61010-1:2000-22	Safety requirements for electrical equipment for measurement, control and laboratory use; Part 1: General requirements.	EN61010-1:2001

Relevant documentation is kept on file and can be requested at the following address: ITC, 8 Olsen Avenue, Edison, NJ 08820, USA.
Telephone 1-732-548-5700/ Fax 1-732-632-9299

WARRANTY AND REPAIR POLICY
One (1) year limited warranty

ITC warrants the Hgb Pro Professional Hemoglobin Testing System, when purchased new, to be free of defects in material and workmanship and will repair or replace at the manufacturer's option any Hgb Pro meter, that under proper use, exhibits such defects. Under terms of this warranty, the product must be returned, properly packaged, transportation prepaid with proof of purchase to:
ITC, 8 Olsen Avenue, Edison, NJ 08820, Attn: Service Department.

This warranty is granted to the original purchaser for one year from the date of the meter manufacture.

In no event shall ITC be liable for indirect, incidental or consequential damages; the original purchaser's or user's remedies being limited to repair or replacement at the manufacturer's option.

Unauthorized modification of the Hgb Pro Professional Hemoglobin Testing System will void the warranty.

REFERENCES

1. Vengelen-Tyler, V. Ed. Technical Manual, 13th Ed. Bethesda, MD: American Association of Blood Banks. 1999: 753-754.
2. Neuberger, A. and E.L. Tatum, Ed. Frontiers of Biology, North-Holland Publishing Co. 1970, p.18. Hemoglobin and Myoglobin in Their Reactions with Ligands, Antoini, E. and M. Brunori.
3. NCCLS Guidance Document EP7-A, Interference Testing in Clinical Chemistry.
4. NCCLS Document H4-A4, Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture.
5. NCCLS Document H3-A5, Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture.

TECHNICAL ASSISTANCE
For technical assistance, contact ITC Technical Service at 1-800-631-5945 or 1-732-548-5700, fax number 1-732-632-9299 or by email at techservice@itcmed.com. General Hgb Pro product information can be obtained at the ITC website at www.itcmed.com or www.hgbpro.com. NCCLS guidelines can be obtained at www.nccls.org or by calling NCCLS at 1-877-447-1888.

CLIAwaived.com™
CLIAwaived.com - 4332 Corte de la Fonda - San Diego, CA 92130
Toll Free : (888) 882-7739 - Phone (858) 481-5031
FAX: (801) 720-7568 - www.cliawaived.com

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